

dried powder compositions produced by spray-drying. The claims, as amended, are all limited to compositions that are spray-dried. The Platz et al. reference teaches that milled interferon compositions may be aerosolized but says nothing about the importance of using a spray-dried composition. Indeed, the Platz et al. reference teaches away from spray-drying. The Platz et al. specification at page 4, last two lines, continuing to page 5, first two lines, indicates that the polypeptides of the Platz et al. invention may be prepared as a dry powder which is milled to an appropriate particle size. The specification indicates that the milling produces micronized solid particles (page 7, line 6) that show improved dispersion in liquid suspension. Additional improvements are obtained by adding a surfactant to the milled polypeptide powder to inhibit aggregation.

Applicant's spray-dried composition, on the other hand, is not milled, but is spray-dried to achieve its retention of potency, stability and dispersibility. By using Applicant's spray-dried composition no surfactant is needed, contrary to Platz et al. (pps. 7-8). While the Platz et al. application mentions in passing that the milled composition can be administered as a dried powder contained in a capsule or blister pack with a dry powder inhaler, it is clear that the intent of the overall application is to teach a composition where a milled powder is suspended in a liquid propellant with suitable excipients and administered in a metered dose inhalation device. All of the examples provide compositions that are lyophilized, jet milled and suspended in a liquid propellant with excipients. The compositions are then administered from a metered dose inhaler.

In light of these clear differences, it is respectfully submitted that claims 1-8 (as amended) are not anticipated by Platz et al., define patentable subject matter and are presently in condition for allowance.

#### REJECTION OF CLAIM 9 UNDER 35 U.S.C. 103

The Examiner's rejection of claim 9 under 35 U.S.C. 103 as being unpatentable over Platz et al. in view of World Patent Application No. 93/003951 (Patton et al.) is respectfully traversed.

Claim 9, as amended, is drawn to a method for aerosolizing a spray-dried composition of interferon. The Platz et al. reference does not teach the preparation of a spray-dried interferon composition. Platz primarily teaches an aerosol formulation which is a combination of the dried powder, prepared by milling, in combination with a liquid aerosol propellant and excipients. While the milled powder is peripherally mentioned as being deliverable as a dry powder, it is not the real teaching of the patent. Thus, one would not be directed to look at a patent such as Patton et al. in order to find a method for aerosolizing a interferon powder composition. One of ordinary skill in the art might be directed to other liquid aerosol propellants that would be useful for the major teaching of the invention. But even if one would look to Patton et al., one would not be taught the invention of claim 9, because there is nothing in the Platz et al. application that teaches making a spray-dried composition. Thus, Platz et al. in combination with the Patton et al. application would at best teach a method for aerosolizing a different composition.

In light of these differences and the lack of any clear reason to combine Platz et al. with Patton et al., it is respectfully submitted that claim 9, as amended, is not obvious over the cited art, defines patentable subject matter and is in condition for allowance.

#### REJECTION OF CLAIM 10 UNDER 35 U.S.C. 103

The Examiner's rejection of claim 10 under 35 U.S.C. 103 as being unpatentable over Platz et al. in view of Radhakrishnan (U.S. Patent No. 5,049,389 - "'389") is respectfully traversed.

The '389 patent teaches the preparation of certain liposome compositions. The compositions are primarily designed to be useful for the production of steroid/liposome compositions, although interferon is mentioned in passing at page 20 line 55. It is clear that none of the '389 examples discuss interferons and that one of ordinary skill in the art would not be directed to an interferon/liposome composition as a major portion of the invention. But, even if one were directed to that in this particular case, it would be clear that the '389 patent teaches the preparation of liposome compositions. The method of claim 10 is not a method for preparing a liposome composition but is a method for preparing a dried powder

which comprises spray-drying an aqueous mixture of interferon and a carrier under conditions to provide a respirable dry powder. Thus, if one would combine the teachings of Platz et al. with the '389 patent one might be directed to obtain a composition which is a liposome-based composition. But the method claimed in this particular case is not directed towards obtaining a liposome composition but instead is directed to a method for obtaining a spray-dried composition of an interferon and a carrier. The need to go through the complexities of making a liposome composition are obviated by the method of claim 10.

For these reasons claim 10 should be considered patentable over the cited art.

#### NEW CLAIMS 11-17

New claims 11-17 are added to emphasize particularly preferred aspects of the invention. Method claims 11-15 are dependent from claim 10 and are parallel to composition claims 2-6. Support is found in claims 2-6 and in the specification at page 5, lines 12-23; page 5, line 24- page 6, line 6; and page 9, lines 12-19. Composition claim 16 covers a particularly preferred aspect that is a combination of claims 1-5, while claim 17 covers the composition with mannitol as the bulking agent. Support is found in claims 1-5 and the portions of the specification set forth above. No new matter is added.

In summary, it is respectfully submitted that Applicant's invention, in its various aspects set forth in claims 1-17 is patentably distinct over any of the art cited by the Examiner alone or in reasonable combination. For these reasons it is respectfully submitted that the Examiner should allow the claims to issue at an early date. Early notice of allowability is solicited.

If in the opinion of the Examiner, a telephone conference would expedite the prosecution of the subject application, the Examiner is invited to call the undersigned at (415) 843-5104.

Respectfully submitted,

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